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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,807	01/25/2002	Jon Ocel	M190.134.101	9381

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EXAMINER
VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

E

Office Action Summary	Application No.	Applicant(s)	
	10/056,807	OCEL ET AL.	
	Examiner	Art Unit	
	Peter J. Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-53 are pending.

The action is final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-4, 7-18, 24-31, 33-43 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hovda (6,053,172) in view of Unsworth (6,520,927).

Hovda et al. (Hovda) discloses an electrosurgical instrument (10) as part of a system (11) and a method of use comprising:

an elongated shaft (100) with a proximal section, a distal section with a rounded tip (102), and an internal lumen (233, col. 17:28-37) , and further wherein the shaft is adapted to be transitionable from a straight state to a first bent state, the shaft independently maintaining distinct shapes (col. 11:30-35 and col. 18:1-11).

Hovda also discloses a handle (204) and an exterior (18, col. 21:62-64) of the shaft that is electrically non-conductive.

Hovda further discloses a source (21) of conductive fluid and an energy source (28). See column 15:41-45.

Note: although the figures in Hovda neglect to depict a rounded tip, Hovda, indeed discloses that the shape of the electrodes (which dictate the shape of the tip) can be round (col. 28:6). Also see col. 13:39-43 ("hemispherical" describes a rounded tip).

Further, with regards to the Applicant's method claims, two distinct bends are possible in Hovda that is depicted in figure 2. They are the bend at element 101 and the bend at element 104. Both bends are capable of independently maintaining their shapes.

Re: claims 2,3,4: Hovda discloses equidistally-aligned passages (209, fig. 3 or 83, fig. 7c). In figure 7c there are two sets of circumferentially aligned passages (designated by the Examiner as "center" adjacent to inner element 112 and "peripheral" adjacent to outer element 112).

Re: claims 7,8, 9,10, 27,28, and 29, note Hovda (col. 11:30-37 and col. 18:1-11). "Bend angles" as disclosed by the Applicant are the angle the shaft is bent with respect to the linear axis defined by the straightened shaft.

Re: claims 11, 30, 40, see column 7:9-18.

Re: claims 13,14, 31, 32: Hovda discloses an elongate electrode body (104, fig. 4) directly coupled (250, fig. 5) to the handle (204, fig. 2). See column 19: 30-32. The electrodes are electrically insulated (col. 12:18-27, element 102, column 20: 31-34).

Further, the electrode body is inherently malleable. If the body was not malleable, during the pre-surgical manipulation of the instrument (as referred to in col. 11:29-37) to suit the surgical application, the body would break.

Re: claim 15. the insulator (102) is configured to conform to the electrode body in the straight and first bent state (col. 20: 31-36).

Re: claims 16,17,18, Hovda discloses an elongated tube (100) that can be either conductive or non-conductive (col. 17:1-5).

Re: claim 20, Hovda discloses a joint ("bend", col. 17:45-47) that can be controlled by a remote actuator (pull-wire, col. 17:53-59). Note: this pull-wire disclosure does not mean that a pull-wire is required for the Hovda device to independently maintain distinct bent shapes, thereby voiding the rejection. (The Applicant in page 12 lines 11-14 of the instant Specification discloses that the ability to independently maintain a distinct bent shape indicates that a pull-wire or an additional component is not present.) The pull wire asserted in Hovda is for distal control of the device tip but is not required for the device to maintain a distinct bent shape along the device shaft.

Re: claim 26, the presence or lack thereof a discernable drag direction is inherent to the design of the Hovda device.

Re: claim 33,34,35,36, Hovda discloses conductive fluid and energy source switches (col. 12:37-41; 17, 30, 37-39, figure 1; col. 15:65-67, col. 16:1-5, col. 17:42-44).

Re: claims 37 and 38, Hovda discloses a sensor (sensing electrode) in column 9 line 62 through column 10 line 8 and an indicator light (fiber optic head light) attached to the instrument in column 15: 45-49.

Hovda, however, does not expressly disclose the use of Nitinol, which would anticipate a shaft adapted to be transitionable from a straight state to a first bent state, the shaft independently maintaining distinct shapes in the straight state and the first bent state (this language is found in the Applicant's independent claims).

Hovda does disclose a shaft made of nickel alloys (ex. nickel titanium) and titanium alloys (ex. nickel titanium). Unsworth expressly discloses a shaft made of Nitinol (ex. nickel titanium; see col. 3:33-38; col. 4:50). The Office contends that this disclosure makes obvious the use of a Nitinol shaft with the Hovda invention and hence the Applicant's currently claimed invention. The motivation to use Nitinol is to provide a material well-known for its versatile usage.

2. Claims 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hovda in view of Unsworth and further in view of Schroeppel ('038).

The steps in claims 44-50 are deemed obvious. The Examiner respectfully asserts that these are steps that would be second nature to any surgeon during a surgery involving an electrosurgical device involving a Nitinol shaft.

An example of surgical manipulation of a tubular medical device with a Nitinol shaft is seen Schroeppel, which discloses a tubular apparatus (Nitinol) that allows physicians/surgeons to determine the shape of a medical device such as a catheter to be inserted into the body. Schroeppel mentions the disadvantages in prefabricating medical devices to be inserted into the body (col. 1:35-53). One disadvantage is that prefabricated medical devices, such as catheters, do not fit for all anatomies. Providing the surgeon with a means to manipulate/mold the dimensions of the catheter through the use of a Nitinol shaft circumvents this problem.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Hovda in view of Unsworth and further in view of Schroeppel by including a method in which a tubular medical device is shaped by a physician as determined by the application. The motivation to do so would be to increase the number of applications/anatomies for which the device could be used.

3. Claims 1-11, 13-16, and 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hovda in view of Unsworth and further in view of Panescu et al. ('267).

Hovda neglects to expressly disclose a tip with a uniform radius of curvature.

Panescu discloses an electrosurgical instrument with a rounded tip in figure 2a that is nearly identical (geometrically, structurally) to that disclosed by the Applicant. As a result the Applicant's claims with regards to discernible drag and other operational or

structural characteristics (ex. uniform radius of curvature) of the instant invention are made obvious.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Hovda in view of Unsworth and further in view of Panescu by including a rounded device tip. The motivation to substitute the device tip in Hovda with that in Panescu would be to improve cooling of the tip electrode as posited in Panescu column 6:23-26, as well as to permit lateral (with respect to the linear axis of the shaft) energy application in addition to forward or longitudinal application.

4. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hovda in view of Unsworth and further in view of Moaddeb et al. ('078).

Hovda neglects to expressly disclose gluing the distal tip of the instrument to the elongated shaft.

Moaddeb et al. discloses an analogous electrosurgical instrument in which gluing the distal tip to the elongated shaft is submitted in column 6:26-28.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Hovda in view of Unsworth and further in view of Moaddeb by including an analogous electrosurgical instrument in which gluing the distal tip to the elongated shaft is disclosed. The clear motivation would be to prevent the device from falling apart.

5. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hovda in view of Unsworth and further in view of Knoepfler ('087).

Knoepfler discloses an analogous device with a pin (42) and remote actuation.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Hovda in view of Unsworth and further in view of Knoepfler by including an analogous electrosurgical instrument in which a pin to permit remote actuation is part of the design. The clear motivation would be to provide distal tip control to the operator.

6. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hovda in view of Unsworth and further in view of Knoepfler ('087) in view of Borst et al. ('688).

Borst et al. (Borst) discloses ball bearing joints (84, col. 8:13-20) in an analogous device.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Hovda in view of Unsworth and further in view of Knoepfler and even further in view of Borst by including an analogous electrosurgical instrument in which a ball bearing joint to permit remote actuation is part of the design. The clear motivation would be to provide distal tip control to the operator.

Response to Arguments

7. Applicant's arguments filed 9-20-05 have been fully considered but they are not persuasive. The Applicant argues that the Office in the Hovda in view of Unsworth rejections lack motivation to combine because of their different intended uses or minor structures. **The Office respectfully contends that Hovda's disclosure of nickel alloys and titanium alloys for shaft material includes an implicit disclosure of Nitinol, which is not rigid, and which is fully capable, when used to design a catheter shaft, of independent maintenance of distinct shapes as found in the Applicant's claims. The Office is not dismissive of the Applicant's arguments and has in response provided art (Unsworth) toward an analogous device, which expressly discloses that Nitinol is a nickel alloy and is used to comprise a catheter shaft.** The combination of the patents is only to show a Nitinol (expressly equated to nickel alloy) catheter in Unsworth to reaffirm the implication in Hovda that a catheter shaft made of nickel alloy or a titanium alloy as disclosed in Hovda col. 17:4-10 makes obvious a Nitinol based catheter shaft, which is well-known for being able to independently maintain distinct shapes as found in the Applicant's claims. Pointing out the different intended uses or minor structures of the patents to question their combination in the rejection is not relevant in this context.

The Applicant argues that Hovda does not teach an entirety of a shaft that is transitionable as claimed in new claim 53. The Office responds that Hovda discloses a shaft comprising a nickel alloy (such as Nitinol) in col. 17:4-10 and that this at the very least suggests the entire shaft is made of Nitinol and is hence capable of independently maintaining first and second shapes as claimed by the Applicant.

Prior arguments are below, that still apply.

The Office now maintains that the express disclosure in a patented analogous invention (Unsworth, see col. 3:33-38; col. 4:50) of the link between nickel alloy shafts and Nitinol (which is fully capable of comprising a shaft that maintains independent shapes) is sufficient to prevent allowance of the claims (note: numerous Hovda patents are listed in Unsworth). The Examiner's obligation is to construe claims and patents **broadly.** Here is an example of this textbook approach. Further, the patents are not to be construed in a vacuum. In other words, they must be viewed in the context of the art. The use of Nitinol is a very common choice in the design of catheter shafts. It is also an example of a nickel or titanium alloy, which is expressly disclosed by Hovda. The Office believes the rationale applied to this case is fair and appropriate.

The Office also notes that the Applicant's arguments are not toward a specific structural element. Instead, the arguments are toward a characteristic of a structural element (catheter shaft). Were examining instrument claims strongly driven by analyzing the nouns involved, this instance would be about analyzing the adjectives used to describe the nouns. In this respect, the Examiner believes the contended language is of lesser patentable weight than if a specific structural element (a noun) were being argued. To strengthen the Applicant's arguments, one could introduce language into the claims regarding a specific structural element (a noun), instead of relying on language that merely describes/characterizes how a structural element relates in space.

Below are more Office provided arguments (slightly adapted to address the change from inherency to obviousness made in this action) copied from the prior final office action dated 5-10-04.

Applicant's arguments filed 3-16-04 have been fully considered but they are not persuasive. The Applicant argues that it is unclear how the curves in shaft 100 (Hovda figure 2) teach or suggest bending a shaft as required by the limitations of claim 39. The Examiner asserts that the curves at elements 101 and 112 suggest bending because a Nitinol (nickel / titanium alloy) shaft on an electrosurgical instrument would not be manufactured / pre-fabricated with curves because it would minimize the number of

applications for which the instrument could be used (discussed in Schroeppel 6,395,038). Also, the Examiner submits that one of the ubiquitous advantages of Nitinol shafts is their ability to be molded/bent into positions as governed by the specific application. For example, if a surgery required traversing a sinuous pathway (such as during intravascular procedures) to access a targeted therapeutic region, curvature of the device at specific places along the shaft could be required. **Hovda is not restricted** to treatment in the larynx, and discloses numerous applications for the patented device in col. 7:9-18.

The Applicant also argues that the curves depicted by Hovda are interpreted as being pre-fabricated to access the larynx. However, as indicated immediately above, Hovda's instrument is for use in numerous applications (col. 7:9-18) including cardiac procedures, intravascular procedures, and gynecological procedures. Certainly, a pre-fabricated bend for treatment of the larynx would not suffice for these other applications. Herein lies the usefulness of a Nitinol shaft. Because the shaft is a nickel/titanium alloy, the instrument can be used in many applications, not just for accessing the larynx.

The Applicant argues that Hovda's disclosure of a nickel/titanium alloy does not necessarily mean disclosure of a malleable type of nickel/titanium alloy (such as Nitinol). However, it is the Examiner's obligation to the public to interpret broadly what is read not only in the application, but also in any patents used to craft rejections. Hovda discloses that nickel titanium alloys can be used as materials for constituting a shaft (col. 17:4-10). Nitinol is a widely known type of nickel titanium alloy, especially known for the construction of electrosurgical device shafts (seen in the catheter in Schroeppel 6,395,038). The Applicant is on the record as saying that the shaft that is adapted to be transitionable from a straight state to a first bent state can be made of Nitinol. Because the Examiner construes Hovda's disclosure as including nickel /titanium alloys, of which Nitinol is ubiquitous in the field of ES devices, one must believe that a Nitinol Hovda shaft would also be adapted to be transitionable from a straight state to a first bent state. On these grounds, the rejections above are based.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos
January 3, 2006

MICHAEL PEFFLEY
PRIMARY EXAMINER